Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Oct 2026

Effect of Psyllium and Flaxseed on glucose, lipids, and constipation in patients with type 2 diabetes and chronic constipation

Protocol summary

Study aim

To compare effects of psyllium and flaxseed supplement versus those who received a placebo on glycemic and lipids control and constipation in patients with type 2 diabetes (T2D) and chronic constipation.

Design

single-blinded, randomized controlled trial. 90 patients with T2D and chronic constipation will receive either 10 grams of psyllium mixed in biscuit twice per day or 10 grams of flaxseed mixed in biscuit twice per day or placebo biscuit for 12 weeks. Fasting plasma glucose, glycosylated hemoglobin (HbA1c), and lipid profile, as well as the constipation score, will be determined at the beginning and end of 4, 8, and 12-week period. constipation will be a score on the ROME III rating scale .

Settings and conduct

This is a single-blinded, randomized placebo-control trial of 90 consecutive patients with T2D and symptoms of chronic constipation attending outpatient clinics in Isfahan Endocrine and Metabolism Research Center .

Participants/Inclusion and exclusion criteria

Patients will be included if they had a bowel movement frequency of < 3/week during the past three months; age ≥30 years and diabetes duration > 1 year. Patients will be excluded from the study if they had type 1 diabetes, weight loss, lipid-lowering drug treatment, fiber supplementation, anorectal problems, abdominal pain, and history of opioid use in the last 48 h, any other factors which would interfere with constipation assessment and management, or pre-existing severe cardiac, endocrinological, hematological, hepatic, renal, metabolic, neurological or psychiatric disorders. Pregnant or nursing women will be excluded. Non-compliant patients during baseline or treatment phases as evaluated by taking <75% of either of the test articles during a one-week period throughout the course of the study will be excluded from the evaluable patient data analysis.

Intervention groups

Participants in the control group will be received psyllium and sugar-free orange-flavored maltodextrin cookies for 12 weeks as placebo. The psyllium group will be received 10 g psyllium premixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks. The flaxseed group will be received 10 g flaxseed premixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks.

Main outcome variables

Primary outcome measures will be included analysis of numerical values of constipation intensity. Secondary outcome measures will be included analysis of the body weight, glycemic and lipid control.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110416006202N2**
Registration date: **2017-12-29, 1396/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-29, 1396/10/08**
Update count: **0**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

Mohsen Janghorbani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source
Isfahan Endocrine and Metabolism Research Center

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Psyllium and Flaxseed on glucose, lipids, and constipation in patients with type 2 diabetes and chronic constipation

Public title
Effect of Psyllium and Flaxseed on glucose, lipids, and constipation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients were included if they had type 2 diabetes. A bowel movement frequency of < 3/week during the past three months.

Exclusion criteria:
Patients were excluded from the study if they had weight loss, rectal bleeding abdominal pain history of opioid use in the last 48 h pre-existing severe cardiac endocrinological hematological hepatic renal metabolic neurological or psychiatric disorders Pregnant or nursing women will be excluded Non-compliant patients during baseline or treatment phases as evaluated by taking <75% of either of the test articles during a one-week period throughout the course of the study will be excluded from the evaluable patient data analysis.

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomized according to a preexisting list produced by a computer program that differed from a random number generator only in that it assigned equal numbers of patients to each treatment group, and the group assignments were concealed in an opaque sealed envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
The trial is single-blinded in that patients will be blind to the treatment. Masking of the two treatments was preserved by creating cookies that looked, tasted, and textured identically. The differences in taste were minimal because the prominent flavor was that of the orange-flavor in which cookies was mixed. Because each participant received only one kind of cookie, the participant had no way to compare their cookie with the other.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences ethic committee

Street address
Hezarjerib

City
Isfahan

Province
Isfehan

Postal code
8184935331

Approval date
2015-04-21, 1394/02/01

Ethics committee reference number
IR.MUI.REC.1396.3.464

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

2

Description of health condition studied
Cholesterol and lipid metabolism

ICD-10 code
E78.7

ICD-10 code description
Disorders of bile acid and cholesterol metabolism

3

Description of health condition studied
Elevated blood glucose
ICD-10 code
R73
ICD-10 code description
Elevated blood glucose level

4

Description of health condition studied
BMI
ICD-10 code
Z68
ICD-10 code description
Body mass index [BMI]

Primary outcomes

1

Description
constipation intensity
Timepoint
Beginning, 4, 8, 12 week after intervention
Method of measurement
ROME III

2

Description
body weight.
Timepoint
Beginning, 4, 8, 12 week after intervention
Method of measurement
Body mass index and body weight.

3

Description
lipids .
Timepoint
Beginning, 4, 8, 12 week after intervention
Method of measurement
Routine measurement of total cholesterol, triglyceride, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol,

4

Description
fasting plasma glucose .
Timepoint
Beginning, 4, 8, 12 week after intervention
Method of measurement
Oxidase method.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 2: 10 grams of psyllium mixed in cookies twice per day for 12 weeks. Kamvar Co., Isfahan, Iran
Category
Treatment - Drugs

2

Description
Intervention 1:10 grams of faxseed mixed in cookies twice per day for 12 weeks. Kamvar Co., Isfahan, Iran
Category
Treatment - Drugs

3

Description
Control group: Participants in the control group will be received psyllium, falxseed and sugar-free orange-flavored maltodextrin cookies for 12 weeks as placebo. Kamvar Co., Isfahan, Iran
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine and Metabolism Research Center
Full name of responsible person
Ashraf Aminorroaya
Street address
Sedigheh Tahereh Research omplex, Khoram Ave
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8184935331
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Movahedian
Street address
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8174673461

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research@mui.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan Endocrin and Metabolism Research Center

Full name of responsible person

Noreddin Soltanian

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohsen Janghorbani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Prof.

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Publish paper

When the data will become available and for how long

starting in March 2018

To whom data/document is available

both people in academic and business

Under which criteria data/document could be used

undecided yet

From where data/document is obtainable

From M. Janghorbani janghorbani@yahoo.com

What processes are involved for a request to access data/document

Contact with the corresponding person.

Comments